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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,160	11/01/2001	Ronald Alan Coffee	BER-3.2.050/4167	2938

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EXAMINER	
OH, SIMON J	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,160	COFFEE ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-9,11-16 and 18-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-9,11-16 and 18-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7,8 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 101 and 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 provides for the use of electrohydrodynamic comminution, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 33 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-9,11-16 and 18-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee (WIPO Document No. WO 98/03267) in view of Sturzenegger *et al.* (U.S. Patent No. 4,197,289) and Roche *et al.* (U.S. Patent No. 5,320,855)

The Coffee document discloses processes and apparatuses for forming material by electrohydrodynamic comminution (See Abstract; and Page 4, Lines 1-4). In one aspect, the processes and apparatuses disclosed within the document is capable of producing various solid and partially solid forms, such as fibers, fiber segments, fibrils, droplets, particles, webs, and mats. This formed matter may also contain a biologically active ingredient (See Page 2, Line 12 to Page 3, Line 15). Fibers, fiber fragments, and particles of biological material, such as fibrin or collagen may also be formed using the processes and apparatuses (See Page 6, Lines 13-18). Alternatively, the active ingredient may be provided as a coating or core of the fibers, fibrils, or particles (See Page 5, Lines 7-28). Active ingredients may be supplied onto fibers, fibrils, or droplets in the form or a liquid that is dispensed through an outlet nozzle (See Page 22, Lines 23-33). The reference discloses that fibers have been successfully spun with polyhydroxybutyric acid, a resorbable polymer, and with polyvinyl alcohol, a water-soluble polymer (See Page 19,

Lines 20-23). In the formation of material provided by the methods and apparatuses disclosed in the reference, the supply of the material may be assisted by an air or inert gas flow (See Claim 32; and Page 30, Lines 27-31). When a melt is used as the material to be formed by the apparatuses and processes disclosed in the reference, the temperature of this material may be controlled by quenching using a cold air or inert gas stream (See Page 11, Lines 17-22).

The Sturzenegger *et al.* patent teaches pharmaceutical dosage forms and methods of making thereof that are created by depositing an active ingredient onto a web, which is then unitized by cutting into individual dosage units (See Columns 16-28). The advantage of such as process is that it allows for dosage forms to be manufactured in a continuous process, eliminating the need for bath lot manufacturing (See Column 3 and 4). The web itself is preferably hydrophilic and disintegrable in water or degradable in body fluids (See Column 6, Lines 16-24). In one embodiment, the web is made from a polymeric material that generally comprises an organic film-former, a plasticizer, modifiers such as optional ingredients, and fugitive solvents (See Column 7, Lines 19-28). Film-forming materials include proteins such as gelatin (See Column 7, Lines 37-41). Fugitive solvents may be water, or an organic solvent, such as ethyl alcohol, or a combination of such solvents (See Column 8, Lines 54-60).

The Roche *et al.* patent is used here merely as a teaching reference to show that additives such as saccharin and peppermint flavoring are commonly known in the pharmaceutical arts (See Column 8, Lines 31-58).

It would be obvious to one of ordinary skill in the art to combine the disclosures of Coffee, Sturzenegger *et al.*, and Roche *et al.* into the objects of the instantly claimed invention. One of ordinary skill in the art would be motivated to combine the Coffee and Sturzenegger *et al.* references in order to devise a continuous method of manufacturing dosage forms that utilizes a more sophisticated method of producing a mat that is created from fibers containing an active ingredient. As explained above, the Roche *et al.* patent is relied upon merely as a teaching reference. It is the position of the examiner that one of ordinary skill in the art could combine the collective disclosures of the prior art with a reasonable expectation of success. It is also the position of the examiner that the selection of fish gelatin over gelatin of other sources is not critical, absent a demonstration of criticality by the applicant of this particular selection. The use of a rotatable endless surface, a limitation in Claims 11 and 25, is considered to be obvious in view of the figures provided in the Sturzenegger *et al.* patent, which depict machinery comprising a conveyor belt. Claim limitations containing specific amounts of specific ingredients are considered by the examiner to be attainable by one of ordinary skill in the art through routine experimentation, and are not considered to be critical.

Thus, the instantly claimed invention is prima facie obvious.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjo

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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